

DESIGNED TO MEET YOUR NEEDS

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Included Optional -- Not available

Occupational Health Mode (OC): Intended for occupational health clinics and insurance companies. Performs FVC and bronchodilation tests quick and easy for early detection of work-related lung diseases.

Primary Care Mode (PC): Intended for Primary Care centers. Performs the main tests with interactive help in order to obtain spirometries with similar quality to the ones performed at a specialized center (Spirometry quality control). Helps to detect and follow-up most common respiratory diseases such as Asthma or COPD

Diagnostic Mode (DG): Intended for Pulmonary Function Laboratories specialized in lung diseases, providing the highest spirometry test control. It is the most complete mode that includes Bronchoconstriction Test, Occupational Health and Primary Care modes among other options.



^{*}Available in 2012

EXPERIENCE IS OUR GUARANTEE

RDI

The DATOSPIR touch spirometer has been designed by the RDI department of SIBEL S.A. with the collaboration of the Pneumology Department of the "Hospital de la Santa Creu i Sant Pau de Barcelona" and the Biophysics and Bioengineering Unit of the University of Barcelona, fulfilling the standardization criteria of the ATS/ERS TASK FORCE 2005 & SEPAR.

Quality control program

• Spirometry quality control program:

DATOSPIR touch includes an automatic function for spirometry quality control, based on the recommendations of the National Lung & Health Education Program (NLHEP).

QC Prompts: Helps the technician to provide good instructions to the patient in order to obtain high quality spirometry tests. At the end of a maneuver, an on-screen notification will inform of its acceptability.

QC Grades: At the end of the test, a quality grade from A to F will be shown to indicate the reliability of the results, according to the NLHEP criteria.

• Accuracy verification program:

ATS/ERS 2005 recommends to check periodically volume spirometers.

In order to check that the transducer is measuring correctly, the spirometer includes a simple verification procedure, to be performed in a few seconds if required.

Main features:

- High resolution color touchscreen.
- Internal printer.
- Rechargeable battery.
- 3 operating modes: Primary Care, Occupational Health or Diagnostic.
- Spirometry quality control program: quality grades for tests, accuracy verification, and calibration program.
- \bullet Modules: $\mbox{SpO}_{2},$ MIP-MEP, Sniff and electronic weather station
- Database with more than 3000 tests with graphs
- Tests: FVC, VC, MVV, Bronchodilation, Bronchoconstriction.
- Simultaneous F/V and V/T graphs.
- Adult and pediatric incentive graphs.
- On-screen help.
- Integrated temperature sensor.
- Connectivity via USB, BLUETOOTH, or ETHERNET*.
- Interoperability compatible with HL7 (spirometry CDA)**.
- Suitable for telemedicine.
- PIN available (In compliance with the European standards for data protection, 95/46/EC).

*Ethernet: Connectivity to the Internet for sending tests by e-mail and for remote data monitoring.

**HL7: Health Level Seven is an international standard for the interoperability of

***HL7: Health Level Seven is an international standard for the interoperability o health information systems. (With W20s software) CDA: Clinical Document Architecture.

Transducers























INNOVATION AND TECHNOLOGY



CUSTOMIZATION

| ID | | 80 | | | | |
|------------------|-------|----|-----|----------|----|--|
| Name Surnames | MARIA | | | | | |
| Age | 65 | cm | 156 | Kg | 65 | |
| Ethnic F. | 100 | | | Sex | Q | |
| Smoke yrs | 0 | | 10 | Cig./day | 0 | |
| Technician | - | | | | | |
| | | | | | | |
| | | | | | | |

PATIENT DATA



FVC



QWERTY KEYBOARD



PEDIATRIC INCENTIVE



PULSE OXIMETRY



QUALITY CONTROL



OPTIONAL MODULES · SOFTWARE

Pulse oximetry

DATOSPIR touch may incorporate a module dedicated exclusively to taking oxygen saturation data and plethysmographic pulse. This option allows you to take pulse oximetry measurements independently or during a spirometry test. It also allows you to visualize the plethysmographic wave in real time and carry out occasional measurements of oxygen saturation (SpO₂) and Pulse Rate (PR) or long-term studies (approximately 8 hours), specially designed for OSAS screening or in any other situation.



Electronic Weather Station

The electronic weather station is a module of the spirometer that measures atmospheric pressure and humidity.

DATOSPIR touch has a built-in temperature sensor as a standard accessory.

The Plug & Play technology of the optional modules allows you to upgrade the spirometer easily by yourself.

W20s software

SIBELMED W20s is a powerful software for the transfer, analysis, storage and/or registration of spirometric signals which operates on Microsoft Windows $^{\circledR}$.

It is compatible with all DATOSPIR spirometers, and its operation can be in real or deferred time, depending on the characteristics of the spirometer. It includes, among other functions:

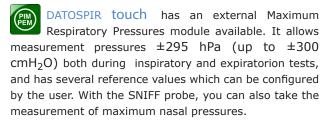
- Patient DB management.
- FVC, VC, MVV tests.
- Bronchodilation tests.
- F/V and V/T graphs.
- Parameter selection.
- Auto diagnosis selection.
- Patient's trend graph.
- Printing reports set up.
- Graphic display, with incentive tests for children and adults.
- Pulse oximetry (SpO₂) and Maximum Pressures Modules (MIP-MEP).
- Compatible with HL7(spirometry CDA). Available in 2012

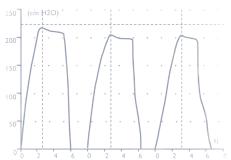
Bronchoconstriction

The bronchoconstriction module is an option available with the DATOSPIR touch spirometer. It has the possibility of performing the test with two different methods:

- Normal or continuous method: It consists of administering a certain concentration of medication to a patient for a specified quantity of time.
- Short method: It consists of administering a patient a certain number of inhalations of a certain concentration to a patient.

MIP-MEP and Sniff

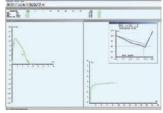




FVC WITH INCENTIVE



BRONCHOCONSTRICTION



• TREND



PULSE OXIMETRY





| MODELS | | Easy | | | Diagnostic | | |
|-----------------------------------|---|------|---|---|------------|---|--|
| | D | Т | F | D | Т | F | |
| TRANSDUCERS | | | | | | | |
| Disposable | | • | • | | • | • | |
| Turbine | • | | • | • | | • | |
| Fleisch | • | • | | • | • | | |
| OPERATING MODES | | | | | | | |
| Primary Care | | | | | | | |
| Occupational Health | | | | | | | |
| Diagnostic | | | | | | | |
| DATABASE | | | | | | | |
| Database >1,000 tests with graphs | | | | | | | |
| Database >3,000 tests with graphs | • | • | • | | | | |
| SOFTWARE | | | | | | | |
| W20s spirometry software license* | | | | | | | |
| CONNECTIVITY / INTEROPERABILITY | | | | | | | |
| USB to external printer and PC | | | | | | | |
| Ethernet | • | • | • | • | | • | |
| HL7 (spirometry CDA)** | • | • | • | • | • | • | |
| Bluetooth | • | • | • | | | | |
| MODULES | | | | | | | |
| Bronchoconstriction | • | • | • | | | | |
| Electronic Weather Station | • | • | • | | | | |
| Pulse oximetry | • | • | • | • | • | • | |
| MIP-MEP | • | • | • | • | • | • | |
| Sniff | • | • | • | • | • | • | |
| ACCESSORIES | | | | | | | |
| Thermal Paper 110 x 50 mm | | | | | | | |
| Reusable mouthpiece | | | | | | | |
| Cardboard mouthpiece (25u) | | | | | | | |
| Disposable transducer (25u) | | | | | | | |
| USB cable for PC / printer | | | | | | | |
| Nose clip | | | | | | | |
| External power supply | | | | | | | |
| User manual | | | | | | | |
| Rechargeable battery | • | • | • | • | • | • | |
| Calibration syringe | • | • | • | • | • | • | |
| Carrying bag | • | • | • | • | | _ | |

Parameters

FVC / Bronchodilation

- FVC (I)
- FEV1 (I)
- FEV1/FVC (%)
- PEF (I/s)
- FFF50%(I/s)
- FEF25-75% (I/s)
- FEV6 (I)
- FEV1/FEV0.5 (-)
- PEFT
- Vext (I)
- FIVC (I) • FIF50%
- FEF50/FIF50
- OC Grades
- FEV.5 (I)
- FEV3 (I)
- FEV.5/FVC (%)
- FEV3/FVC (%)
- FEV1/VC (%) • FEV1/FEV6 (%)
- FEV1/PEF (%)
- FEV1/FIV1 (-)
- PEF/PIF (-)
- FEF25% (I/s)
- FEF75% (I/s)
- FEF75-85% (I/s)
- FET25-75 (s)
- FET100 (s) • FIV1 (I)
- FIV1/FIVC (%)
- PIF (l/s)
- MTT (s)
- MVVInd (I/min)
- COPD Index (%)

References

SEPAR

CRAPO

KNUDSON

• ZAPLETAL

MORRIS

AUSTRIA

GUTIERREZ

CASTRO-PEREIRA

• FRS

• Lung age (years)

VC

- VC (I)
- TV (I)
- ERV (I) • IRV (I)
- IC (I)
- Ti (s)
- Te (s)
- Tt (s) • Ti/Tt (%)

- MVV (I/min)
- Br./min (Br/min)

Bronchoconstriction

- FVC (I)
- FFV1 (I)
- PEF (I/s)
- FEF25-75% (I/s)

Sp0₂

- Maximum SpO₂ (%)
- Average SpO₂ (%)
- Minimum SpO₂ (%)
- SpO₂ Std Dev (%)
- Maximum PR (BPM)
- Average PR (BPM)
- Minimum PR (BPM)
- PR Std Dev (BPM)
- CT90 (%)
- CT80 (%)
- CT70 (%)
- ODI-4
- ODI-3
- ODI-2

POLGAR-WENG

PEREZ - PADILLA

CRUZ-MORALES

• GOLSHAN

CANDELA

PLATINO

Ask for a free spirometry training course.

• THAI 2000

• GARCIA RIO

 Test time (hh:mm:ss)

• HANKINSON - NHANES III

Technical Specifications

Flow transducer: Fleisch, turbine or disposable (Lilly)

Measurement range (BTPS): Flow 0 ± 16 l/s; Volume 0 to 10 l

Accuracy (BTPS): Flow 5% or 200 ml/s; Volume: 3% or 50ml (ATS/ERS)

Dynamic resistance: <1.47 hPa (<1.5 cmH₂0) / (I/s) at 14 I/sDisplay: 640 x 480 px and 5.7 inch high resolution color VGA touchscreen

Printer: 112 mm thermal graphic printer

Rechargeable battery: Ni-Mh 10.8V 2500mAh. Duration 1.5h approx.

No. of maneuvers per patient: 8 FVC, 8 VC, 8 MVV Operating Temperature-Humidity: 5 to 40°C. < 85% (without condensation)

Power supply: 100 to 240V, 50 to 60Hz

Power: 30W

Dimensions: 195 x 270 x 100 mm

Weight: 1.7 kg

Storage temperature: -20°C to 70°C

Directive: 93/42/CEE on Medical Devices, Class IIa Product Standards: EN 60601-1:2006+AC:2010, EN 60601-1-2:2007+AC:2010, EN 60601-1-6:2010, EN ISO 10993-1:2009+AC:2010, EN ISO 23747:2009, EN ISO 26782:2009+AC:2009, EN 62304:2006+AC:2008, EN 62366:2008, EN 1041:2008, EN ISO 15223-1:2012, EN ISO 14971:2012, ISO 80601-2-61:2011

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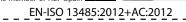
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Sibelmea

FG SIB 1102 - Datospir touch - V.1.2 - 03/201